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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/19/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,338

Applicant(s)

ROTHBERG ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 1-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-87 is/are rejected.
- 7) ☒ Claim(s) 86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 56-70 and 72-87 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that it would not pose an undue burden on the Office to search Groups I, II, III, and IV, effectively all of the inventions. Upon careful reconsideration, Group IV (claim 71) will be rejoined with the elected Group III for prosecution. However, Applicants' arguments drawn to the rejoinder of Groups I and II are not found persuasive because the methods of I and II are materially different resulting in searches that require different consideration (i.e., enablement, obviousness, etc.) for patentability determination. Therefore, searching the method claims of Groups I and II with the instantly elected Group III (and rejoined Group IV) would pose a search burden on the Office. Further, an application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are independent (MPEP 806.04-806.04(j)) or distinct (MPEP 806.05-806.05(i)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Preliminary Remark

Claims 56-87 are under prosecution.

Specification

This application claims priority to a parent application, U.S. Application Serial Number 09/398,833, which is now a U.S. Patent No. 6,274,320. However, the status of the parent application is not updated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 (and its dependent claims) recites the limitation "the plurality of microparticles." There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 86 is objected to for being dependent on a proceeding claim.

A series of singular dependent claims is permissible in which a dependent claim **refers to a preceding claim** which, in turn, refers to another preceding claim. See MPEP § 608.01(n).

For the purpose of prosecution, claim 86 is assumed to be dependent on claim 85.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 56-58, 64-70, 72-78, and 84-87 are rejected under 35 U.S.C. 102(a) as being anticipated by Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15).

Claims 56-58, 64-70, 72-78, and 84-87 are drawn to a substrate and apparatuses comprising a cavitated fiber optic surface and a nucleic acid (or an anchor primer) fixed to the fiber optic surface. Some embodiments are drawn to the substrate comprising a plurality of fiber optic surfaces.

The present art rejection is applied with the definition supplied by the specification wherein, “anchor primers” are defined as being oligonucleotides (pp. 10, line 23) and the “anchor pad” is defined as being a region of substrate containing a linked primer (pp. 12, lines 5-6).

Walt et al. disclose a plurality of optical fibers each of which has a cross-section diameter (or substrate) of 5-500 μm (pp. 14, line 18-19) bundled co-axially along their lengths to form an array (pp. 13, lines 24-30). Walt et al. disclose that each fiber need not be constrained to a specific form, such as planar (pp. 14, line 26) though most desirable. Other forms of fibers are disclosed wherein one of the contemplated forms have “depressions or well” which extends into the substance of the optical fiber, or in other words “cavitated” (pp. 15, lines 27-30). Walt et al. explicitly disclose nucleic acid probes (i.e., DNA, RNA, PNA, or oligonucleotides) being fixed

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on the surface of the optical fibers for hybridization assays (pp. 13, lines 20-25). For a conventional array of 200 μ M diameter, it is disclosed that 2000 to 3000 optical fibers strands could be bundled, translating to 2000 to 3000 optical fiber strands in a surface area of 3.1×10^{-4} cm² (pp. 19, lines 5-8). Lastly, Walt et al. disclose an apparatus comprising an optical array which further comprises bundles of fiber optic strands having nucleic acid probes fixed therein (Figure 16).

Therefore, Walt et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15) in light of Pantano et al. (Chemistry of Materials, 1996, vol. 8, no. 12, pp. 2832-2835).

Claims 56-58, 64-70, 72-78, and 84-87 are drawn to a substrate and apparatuses comprising a cavitated fiber optic surface and a nucleic acid (or an anchor primer) fixed to the fiber optic surface. Some embodiments are drawn to the substrate comprising a plurality of fiber optic surfaces.

Claim 71 is drawn to a fiber optics array made by process of photolithography.

Claims 59-63 and 79-83 are drawn to various distances between anchoring primers.

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The teachings of Walt et al. for claims 56-58, 64-70, 72-78, and 84-87 are iterated above.

Walt et al. do not explicitly disclose the various spacing between the primers nor the process of making an array via photolithography.

Pantano et al. Disclose a 100 μ m-diameter imaging fiber (or substrate) array which is comprised of approximately 70,000 individually cladded optical fibers (pp. 2833, 1st column, Figures 1 and 2). Each fiber is disclosed as being "chemically etched" or cavitated (pp. 2833, 1st column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Walt et al. with the well known knowledge in the art of microarray fabrication as demonstrated by Pantano et al. to arrive at the invention as claimed for the following reasons.

Although Walt et al. do not explicitly teach the claimed spacing between the primers or the anchor pads, Pantano et al. contemplates various spacings between the nanowells or the array (or the anchor pads as defined by the specification), wherein the center-to-center spacing of array of wells was manipulated (pp. 2833-2834), clearly demonstrating that such modification is well within the purview of an ordinarily skilled practitioner. Because the teachings Pantano et al. were also directed in the field of fiber optic biosensors, an ordinarily skilled practitioner would have had a reasonable expectation of success in modifying the distance between the primers (probes) or anchor pads taught by Walt et al.

As to claim 71 drawn to a fiber optic array produced by the photolithography method, such method of array production is well-known in the art of microarray fabrication and the

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produced product (array) is determined to be structurally identical to the array produced by the cited artisans. MPEP 2113 states that:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself...If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Therefore, the invention as claimed is obvious over the cited references.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 56, 57, 64-67, 69, 70, 71, 73, 74, 76, 77, 84, and 85 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33, 35, 41-44, 45, 46, 47, 49-52, 59, and 60 of copending Application No. 09/664,197. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application

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since the referenced copending application and the instant application are claiming common subject matter, as follows: claims are drawn to a cavitated fiber optic substrate, and an apparatus comprising the substrate. More specifically, the claims are identical in their scope as illustrated below:

Claims of the Instant Application	Claims of Application Serial No. 09/664,197
56	33
57	35
64-67	41-44
69-71	45-47
73-74	49-50
76-77	51-52
84-85	59-60

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-62 of copending Application No. 09/664,197. Although the conflicting claims are not identical, they are not patentably distinct from each for the following reasons.

Applicants are advised of the non-obviousness rejection of claims 56, 57, 64-67, 69, 70, 71, 73, 74, 76, 77, 84, and 85 over claims 33, 35, 41-44, 45, 46, 47, 49-52, 59, and 60 of copending Application No. 09/664,197. The instant rejection includes the above rejected claims for the sake of clarity and should not be confused as to why the same claims are being rejected again under obviousness.

The independent claims 56, 64, 69, 73, and 84 of the instant application are identical to the independent claims 33, 41, 45, 49, and 59 of the '197 Application. The dependent claims 57, 65-67, 70, 71, 74, 76-77, and 85 of the instant application are identical in form and scope to the dependent claims 35, 42-44, 46, 47, 50-52, and 60. The remaining dependent claims 58-63, 72, 78-83, 86, and 87 are identical in form but slightly different in their scope from the remaining dependent claims 34-40, 48, 53-58, 61, and 62. However, the difference in scope is does not patentably distinguish each other in their invention because the claimed inventions are an obvious variant of each other (only in scope). As to claims 68 75 of the instant application which is drawn to an embodiment of oligonucleotide primers being covalently attached to the

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substrate surface of an array and wherein the substrate is a cavitated planar surface, such modification is well known in the art of array fabrication as well as disclosed in the specification of the copending application, and is therefore considered to be an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.


Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

11/18/02




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

11/18/02